## Simple Letter Agreement for the Transfer of Material to PHS-Funded Scientists and PHS Contractors

In response to RECIPIENT's request for MATERIAL (meaning sample of Cellartis AB's	
Human Embryonic Stem Cells, ref:	, and its unmodified and undifferenti-
ated progeny or derivatives) for a research program entitled	
Cellartis AB ("PROVIDER") asks that the RE	CIPIENT and the RECIPIENT SCIENTIST

- 1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community. Ownership of the MATERIAL shall remain with PROVIDER and transfer of the MATERIAL to the RECIPIENT shall not affect PROVIDER's ownership of the MATERIAL.
- 2. This MATERIAL is not to be used for diagnostic or therapeutic purposes. As used herein, non-commercial research purposes specifically includes research funded by the US Government but excludes (i) research sponsored by a for-profit entity wherein the sponsor receives rights whether actual or contingent to the results of the sponsored research, and (ii) research sponsored by a non-profit entity wherein the sponsor receives a right whether actual or contingent to the results of the sponsored research other than a grant for non-commercial research purposes to the sponsor. The MATERIAL may not be used for commercial purposes or the direct benefit of research sponsor, except as such research sponsor is permitted to use MATERIAL under a separate written agreement with PROVIDER. Specifically, MATERIAL shall not be used in a PHS research program where rights (either actual or contingent), have already been granted to a research sponsor who does not have a separate written agreement with PROVIDER permitting such use of MATERIAL, except where the rights granted to a research sponsor are limited to a grant to use RECIPIENT's intellectual property or materials for noncommercial research purposes.
- 3. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the

PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or non-commercial research purposes only.

- 4. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it and to provide PROVIDER a copy upon actual publication.
- 5. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages which may arise from the use, storage, handling or disposal of MATERIAL except that, to the extent permitted by law, PROVIDER shall be liable to the RECIPIENT when the damage is caused by the gross negligence or willful misconduct of the PROVIDER.
- 6. The RECIPIENT agrees to use the MATERIAL only in compliance with all applicable statutes, regulations and guidelines relating to the RECIPIENT's handling, use or disposal of the MATERIAL. The RECIPIENT shall not use the MATERIAL in humans or in contact with any cells or other materials to be transferred into humans. Use of the MATERIALS to prepare somatic cell therapy product or gene therapy products is specifically prohibited. Specifically, where the MATERIALS are cells, the RECIPIENT will not reintroduce these cells alone or in combination with other cells into the reproductive tract of a female animal, nor use these cells for purposes of in-vitro culture with human or animal zygotes or embryos.
- 7. In the course of use of the MATERIALS, RECIPIENT and RECIPIENT SCIENTIST may create Derivative Material. "Derivative Material" shall be defined as any materials or products

- a) that are physically derived from the Material including without limitation, differentiated cell lines or differentiated or populations derived from the MATERIAL, and any unmodified products of such cell lines or populations (i.e. RNA, DNA, proteins, cellular components of fragments thereof) or
- b) that wholly or partially contain or incorporate the MATERIAL.

Upon PROVIDER's written request, RECIPIENT and RECIPIENT SCIENTIST hereby agree to provide to PROVIDER reasonable quantities or samples of such Derivative Material without cost only after RECIPIENT and RECIPIENT SCIENTIST have publicly disclosed or reasonably characterized such Derivative Material. The U.S. Public Health Service (PHS), Department of Health and Human Services, agrees to continue its current policy of retaining the right to grant internal use research licenses to either non-profit or for-profit institutions for inventions assigned to the PHS. RECIPIENT and RECIPIENT SCIENTIST shall promptly notify PROVIDER upon creation and characterization of Derivative Material that become the basis of related applications claiming intellectual property rights.

- 8. The MATERIAL is provided with a transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. The amount of the fee for this transfer of MATERIAL will be indicated here: \_\_\_\_\_\_ (\$6,000 USD per sample of a defined cell line provided). This transmittal fee does not include any costs associated with training RECIPIENT in cell growth and maintenance.
- 9. This agreement shall enter into effect on the date of the last party to execute this agreement and shall remain in effect as long as the research is continued under this agreement. This agreement may be terminated by either the PROVIDER or the RECIPIENT by a notice in writing with immediate effect if the other party is in breach of any of the terms or conditions of this agreement. Notwithstanding the termination or expiration of the agreement, Section 1, Section 3 through 5, Section 7, Section 9 and Section 10 shall remain in effect.
- 10. The RECIPIENT and/or the RECIPIENT SCIENTIST shall at the request of the PROVIDER either destroy or return the Material to the PROVIDER in case i) this

agreement is terminated or expired, ii) the relevant donor consent is withdrawn, iii) approval from Ethics Committee is not obtained or withdrawn or iv) the PROVIDER otherwise is obliged to cause the Material to be returned or destroyed.

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

Provider Scientist:
Provider Organization:
Address:
Name of Authorized Official:
Title of Authorized Official:
Signature of Authorized Official:
Date:
RECIPIENT INFORMATION and AUTHORIZED SIGNATURE
Recipient Scientist:
Recipient Organization:
Address:
Name of Authorized Official:
Title of Authorized Official:
Signature of Authorized Official:
Date:
CERTIFICATION
Certification of Recipient Scientist: I have read and understood the conditions outlined in this
Agreement and I agree to abide by them in the receipt and use of the MATERIAL.
Recipient Scientist:
Date: